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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,763	06/23/2003	Jeffrey A. Von Arx	279.599US1	7304
21186	7590	02/23/2006		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			EXAMINER JOHNSON, SHEVON ELIZABETH	
			ART UNIT 3766	PAPER NUMBER
DATE MAILED: 02/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/601,763	ARX ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shevon E. Johnson	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-15, 17-23 and 25-35 is/are rejected.
- 7) ☒ Claim(s) 10-12, 16 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                               |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/9/2005</u> . | 6) <input type="checkbox"/> Other: _____                                                |

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***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language used is incomplete and unclear, wherein 'the message derived from the first or second message includes the first or second message'. Examiner suggests wherein 'the message derived from the first message sent by the IMD or the ED for authentication includes the first message and wherein the message derived from the second message sent by the IMD or the ED for authentication includes the second message'.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 21-23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hooper et al. herein Hooper (U.S. Patent No. 5,080,096), as cited by examiner.**

In regards to claim 1, Hooper inherently discloses a method comprising: implementing a telemetry interlock; releasing the telemetry interlock by transmitting an enable command; authenticating the IMD to the ED when the ED receives a message from the IMD evidencing use of an encryption key expected to be possessed by the IMD; authenticating the ED to the IMD when the IMD receives a message from the ED evidencing use of an encryption key expected to be possessed by the ED; and, allowing a data

communications session between the IMD and ED over the telemetry channel to occur only after the IMD and ED have been authenticated to one other (col. 8, lines 35-47 and col. 11, lines 8-28).

**4. Claims 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Snell et al. herein Snell (U.S. Patent No. 6,907,291), as cited by examiner.**

In regards to claim 1, Snell inherently discloses a method comprising: implementing and releasing a telemetry interlock by transmitting an enable command (col. 7, line 59 thru col. 8, line 2); authenticating the IMD or ED by use of an encryption key; and, allowing a data communications session between the IMD and ED (col. 9, line 49 thru col. 10, line 20, Fig. 4).

**5. Claims 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (U.S. Patent Pub. 20010027331), as cited by the applicant.**

In regards to claims 27-30, Thompson discloses a method comprising: authenticating the IMD or ED to the ED or IMD when the IMD or ED receives a message from the IMD or ED evidencing use of an encryption key (i.e. symmetric, asymmetric keys or secret keys) expected to be possessed by the IMD or ED; and, allowing a data communications session between the IMD and ED over the telemetry channel to occur only after the IMD or ED has been authenticated to the IMD or ED (pg. 5, [0033], lines 1-7, [0034], lines 23-41; and pg. 6, [0045], fig. 5). Note that the reference also teaches that any arrangement of devices may be used (pg. 5, [0032], lines 9-16, Fig. 4).

***Claim Rejections - 35 USC § 103***

**6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**7. Claims 1-3, 5-6, 8, 14-15, 21-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper '096 in view of Thompson (U.S. Patent Pub. 20010027331).**

In regards to claims 1, 2, 3, 5, 6, 8, 14-15, 21-23 and 25-26, Hooper discloses the method substantially as stated in claims 1, 8, 14-15, 21-23 and 25-26, comprising: implementing a telemetry

interlock, releasing the telemetry interlock, an authentication process, then allowing a data communications session between the IMD and ED (col. 8, lines 35-47 and col. 11, lines 8-28). Hooper fails to disclose an authentication process wherein the ED and the IMD are authenticated to one another using public/private cryptography and personal device identity codes, as pertains to claims 2 and 5. However, Thompson teaches a method wherein devices transmits and receives digital signatures to one another to validate the authenticity of a communication, in addition, these digital signatures can be sent along with sensitive information (pg. 5, [0035]). Thompson further teaches the method wherein the authentication process involves the distribution of asymmetric keys (i.e. public/private keys) between devices (pg. 5, [0033], lines 1-7, [0034], lines 23-28; and pg. 6, [0045], fig. 5), as pertains to claims 2, 3, 5, and 6. Note that the reference also teaches that any arrangement of devices may be used (pg. 5, [0032], lines 9-16, Fig. 4).

One having ordinary skill in the art would appreciate that Hooper and Thompson could be combined since they both teach methods for enabling secure communication between an implantable medical device and external device, and thus the references are analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Hooper by incorporating an enhanced authentication protocol using digital signatures and public and private key cryptography as taught by Thompson in order to provide privacy to patient data through added security to the telemetry process (pg. 2, [0005], lines 1-15).

**8. Claims 9 and 13 are rejected base upon the arguments presented for the rejection of claims 1 and 2 above as being unpatentable over Hooper '096 in view of Thompson (U.S. Patent Pub. 20010027331).**

Thompson teaches the method of claim 2 further comprising encrypting communications between the ED and IMD during the data communications session with secret key cryptography as described in claim 9 and 13, wherein the secret key data communications session is established by one of either the ED or the IMD transmitting to the other of either the ED or the IMD a secret session key encrypted by the latter's public key (pg. 5, [0034], lines 30-41).

**9. Claims 1, 2, 4, 7-8, 17-23, 25-26 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell '291 in view of Thompson (U.S. Patent Pub. 20010027331).**

In regards to claims 1, 2, 4, 7-8, 21-23, and 25-26, Snell discloses the method substantially as claimed as presented above further including first and second messages with random numbers generated by the ED and IMD, respectively (col. 10, lines 60-65, fig. 7). The reference also teaches a method wherein the message derived from the first message transmitted by the IMD includes the second message (col. 11, lines 49-61, fig. 9). Snell fails to disclose an authentication process wherein the ED and the IMD are authenticated to one another using public/private cryptography. However, Thompson teaches the method wherein the authentication process involves the distribution of public/private keys between devices (pg. 5, [0033], lines 1-7, [0034], lines 23-28; and pg. 6, [0045], fig. 5), as pertains to claim 2.

In regards to claims 17-20, Snell discloses a method wherein the telemetry channel includes communications links, such as magnetic link, an inductive link or the like (col. 6, lines 50-59) and wherein a magnet actuates the telemetry interlock. Thompson teaches a method wherein the telemetry channel includes communications links (pg. 5, [0031]).

In regards to claims 32-35, Snell inherently discloses the device including a an implantable medical device 132, external devices 108 and 109, means for implementing and releasing the telemetry interlock, a magnet may be placed over magnetic detection circuitry 87 actuating the communication channel/link (col. 7, line 59 thru col. 8, line 2, fig. 1). Thompson discloses an implantable medical device 132, external devices including programmers (112, 114, 116, 118), computer/programmer 122, encryption/decryption engine 230 and 234, sensitive data 221 and a key source 228 (pg. 5, [0032 and 0033], Fig.4).

One having ordinary skill in the art would appreciate that Snell and Thompson could be combined since they both teach methods for enabling secure communication between an implantable medical device and external device, and thus the references are analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Snell by incorporating an enhanced authentication protocol using public and private key cryptography as taught by Thompson in order to provide enhance security for patient data (pg. 2, [0005], lines 1-15).

***Allowable Subject Matter***

Claims 10-12, 16 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Citation of Relevant Prior Art***

The prior art made of record and not relied upon but considered pertinent to applicant's disclosure includes Sholder et al. (U.S. Patent No. 5,074,308) and Barreras (U.S. Patent No. 5,807,397) which relates to a communications system for medical devices.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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